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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 114/13PCT	FOR FURTHER ACTION	See item 4 below
International application No. PCT/US2004/008066	International filing date (<i>day/month/year</i>) 18 March 2004 (18.03.2004)	Priority date (<i>day/month/year</i>)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant ARCUS MEDICAL, LLC		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
2. This REPORT consists of a total of 5 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.
3. This report contains indications relating to the following items:

<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input type="checkbox"/> Box No. II	Priority
<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input checked="" type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/> Box No. VI	Certain documents cited
<input type="checkbox"/> Box No. VII	Certain defects in the international application
<input type="checkbox"/> Box No. VIII	Certain observations on the international application
4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Date of issuance of this report 20 September 2006 (20.09.2006)
	Authorized officer Dorothee Mülhausen e-mail: pt01@wipo.int

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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REC'D 02 MAR 2006

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference 114/13PCT		Date of mailing (day/month/year) 27 FEB 2006
FOR FURTHER ACTION See paragraph 2 below		
International application No. PCT/US04/08066	International filing date (day/month/year) 18 March 2004 (18.03.2004)	Priority date (day/month/year)
International Patent Classification (IPC) or both national classification and IPC IPC(8): A61F 5/44 and US Cl.: 604/349		
Applicant ARCUS MEDICAL, LLC		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer <div style="text-align: center;"> Tatyana Zalukagva </div> Telephone No. (571) 272-3700
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Form PCT/ISA/237 (cover sheet) (January 2004)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US04/08066

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/08066

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:
- ☐ paid additional fees
- ☐ paid additional fees under protest
- ☒ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
- ☒ not complied with for the following reasons:
- See the lack of unity section of the International Search Report (Form PCT/ISA/210)

4. Consequently, this opinion has been established in respect of the following parts of the international application:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-9 (Group I)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US04/08066

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>NONE</u>	YES
	Claims <u>1-9</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-9</u>	NO
Industrial applicability (IA)	Claims <u>1-9</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-9 lack novelty under PCT Article 33(2) as being anticipated by Choksi (US 5,727,594).

With respect to claim 1, Choksi discloses a collection bag (76) adapted for communicating with a male incontinence device fully capable of covering a portion of the penis, the collection bag (76) comprising first and second flexible side walls joined together and forming a fluid container for holding urine (fig. 1); and a cylindrical bag neck (74) defining a mouth for receiving urine, the bag neck comprises a rigid valve cap (10), the valve cap (10) comprising an internal check valve (54); multiple circumferentially-spaced indexing elements (66) cooperating to position valve cap such that the check valve is locatable in a single operative orientation (col. 2, ll. 13-22).

With respect to claim 2, Choksi discloses in Figures 3 and 4 the valve cap comprises an enlarged-diameter connecting portion (14) and reduced diameter cylindrical valve housing (16, 24) containing check valve (54). With respect to the limitation of "integrally-formed", Choksi discloses integrally (col. 6, l. 66-67) and separably (col. 7, ll. 48-61) formed, however the method of forming the device is not germane to the issue of patentability of the device itself, therefore this limitation has not been given patentable weight.

With respect to claim 3, Choksi discloses indexing elements (66) spaced-apart along an inner circumference of the connecting portion (fig. 8) of the valve cap (10).

With respect to claim 4, Choksi discloses in Figures 11-13 an outer circumference of the connecting portion (86) comprises visual markers (84, 90).

With respect to claim 5, Choksi discloses a perforated (68) inlet wall (24) within valve housing (16).

With respect to claim 6, Choksi discloses the check valve (54) comprises a pivoted disk (60) residing in a normally closed position (col. 5, l. 32) seated against perforated (68) inlet wall (24) and under a minimum crack pressure (col. 5, l. 40) pivoted disk moving to temporarily open position to allow free fluid flow (col. 5, ll. 23-45) to fluid container (76).

With respect to claim 7, Choksi discloses a retainer ring (58) in side valve housing holding pivoted disk (60) in position against perforated (68) inlet wall (24).

With respect to claim 8, Choksi discloses the pivoted disk (60) is formed of flexible elastomer (col. 4, ll. 46-47, col. 6, ll. 50-53).

Claim 9 lacks an inventive step under PCT Article 33(3) as being obvious over Choksi in view of Nilsson (US 4,753,642).

With respect to claim 9, Choksi does not expressly disclose at least one of the flexible side walls is at least semi-transparent. Nilsson teaches a collection bag and valve arrangement adapted for communication with a male incontinent device designed to cover a portion of the penis (col. 5, ll. 39-40). Nilsson discloses one of the side walls is semi-transparent (col. 2, ll. 63-68). Nilsson states that the benefit of making the collection bag with this design is that it shows the volumetric content of the bag thereby alerting the user when the bag is full and can be drained of urine for reuse (col. 5, ll. 2-5). In view of the teachings of Nilsson, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the bag of Choksi having at least one wall semi-transparent as taught by Nilsson in order to show when the bag is full of fluid.

Claims 1-9 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.